ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collections of information to OMB for review and clearance.

Petition For Administrative Reconsideration of Action—21 CFR 10.33—(OMB Control Number 0910–0192—Reinstatement)

Section 10.33 (21 CFR 10.33), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may petition the Commissioner of Food and Drugs (the Commissioner) for reconsideration of an agency's action. A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. Each petition must be submitted no later than 30 days after the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.33(b)	7	1	7	10	70

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Due to a typographical error, the total burden hours were reported as 700 in FDA's December 16, 1997 (62 FR 65812), notice providing 60 days for public comment on this collection of information. The total has been corrected to 70. The burden estimate for this collection of information is based on agency records and experience over the past 3 years. Agency personnel handling the petitions for administrative reconsideration of an action estimate approximately seven requests being received by the agency annually, each requiring an average of 10 hours preparation time.

Dated: March 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7893 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on May 13, 14, and 15, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 13, 1998, the committee will discuss the science of corticosteroid induced osteoporosis. On May 14, 1998, the committee will discuss new drug application (NDA) 20–866, Ergoset™, (bromocryptine mesylate, Ergoscience) as monotherapy as an adjunct to diet to improve glycemic control in patients with non-insulin-dependent diabetes mellitus, whose hyperglycemia cannot be satisfactorily managed with diet alone; or concomitantly with a sulfonylurea when diet and Ergoset™ alone do not result in glycemic control. On May 15, 1998, the committee will discuss NDA 20–898, Thyrogen™, (thyrotropin alpha, rTSH, Genzyme) as an adjunct for the detection of thyroid cancer.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 8, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on May 13, 14, and 15, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 8, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 19, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–7897 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F